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10/672,660

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EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT

PAPER NUMBER

3766

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/672,660

Applicant(s)

THACKER ET AL.

Examiner

Kristen Droesch Mullen

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 22-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36-51 is/are allowed.
- 6) ☒ Claim(s) 1-3,22-24,26 and 35 is/are rejected.
- 7) ☒ Claim(s) 25 and 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the joystick must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 is inaccurate because the electrical pulse generator does not comprise a joystick. The programmer includes the joystick.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-2, 22-23, 26, are rejected under 35 U.S.C. 102(e) as being anticipated by Bradley (2003/0093134).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Regarding claim 1, Bradley shows obtaining a stimulation parameter set, providing stimulation to a selected region of a spinal cord in accordance with the stimulation parameter set, obtaining a level of power consumption of the stimulation parameter set, repeating the steps for each of a plurality of different stimulation parameter sets and determining a low power consumption stimulation parameter set based, at least in part, on the levels of power consumption respectively associate with the different stimulation parameter sets (paras. [0013], [0023], [0038], [0042]).

With respect to claim 2, Bradley shows obtaining the stimulation parameter set comprises selecting one of a multiple of stimulation parameter sets and adjusting the stimulation level of the parameter set to find an adequate stimulation level (therapeutic ratio) for achieving sensory parasthesia (Fig. 5; paras. [0036]-[0038]).

Regarding claim 22, Bradley shows obtaining a level of power consumption comprises computing a value of the power consumption (amplitude times duration) (para. [0038]).

With respect to claim 23, Bradley shows the low power consumption stimulation parameter set is selected from the different stimulation parameter sets (Claim 10).

Regarding claim 26, Bradley shows programming the low power consumption stimulation parameter set into a spinal cord stimulation (SCS) implantable pulse generator (IPG) (para. [0038]).

6. Claims 27-29, 31-33 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Mouchawar et al. (6,738,668).

Regarding claim 27, Mouchawar shows a system comprising: an electrical pulse generator configured for providing stimulation in accordance with a plurality of different

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stimulation parameter sets; and a programming device (38) configured for associating levels of power consumption respectively with the different stimulation parameter sets, and determining the low power consumption stimulation parameter set based, at least in part, on the levels of power consumption respectively associated with the different stimulation parameter sets (Fig. 10; Col. 12, line 39-Col. 13, line 9).

With respect to claim 28-29, Mouchawar shows an electrode lead coupled to the pulse generator, furthermore, the pulse generator could be used externally

Regarding claim 31, Mouchawar shows the programming device is further configured for computing the values of power consumption, respectively associating the computed values of power consumption with the different stimulation parameter sets, and determining the low power consumption stimulation parameter set based, at least in part, on the values of power consumption respectively associated with the different stimulation parameter sets (Col. 9, line 13-Col. 13, line 22; Fig. 10).

Regarding claims 32-33, Mouchawar shows a user interface (102, 104, 106) (Fig. 1).

With respect to claim 35, Mouchawar shows the programming device is configured for programming.

The functional language and statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art. Examples of functional language and statements of intended that are not considered to impart any further structural limitations over the prior art are:

- configured for providing stimulation to a selected region of a spinal cord
- spinal cord stimulation (SCS) electrode lead

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- external trial stimulator (ETS)
- configured for allowing a user to select the low power consumption stimulation parameter set from the different stimulation parameter sets
- configured for displaying representations of the different stimulation parameter sets and associated levels of power consumption to a user
- configured for programming the low power consumption stimulation parameter set into a spinal cord stimulation (SCS) implantable pulse generator (IPG).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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9. Claim 24 is rejected under 35 U.S.C. 103(a) as being obvious over Bradley (2003/0093134) as applied to claim 23 above. Bradley shows the user selecting the low power consumption stimulation parameter, but Bradley fails to show displaying representations of the different stimulation parameter sets and associated levels of power consumption to a user, and the user selecting the low power consumption stimulation parameter set from the displayed stimulation parameter set representations. It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Bradley to include displaying representations of the different stimulation parameter sets and associated levels of power consumption to a user and selecting the low power consumption stimulation parameter set from the displayed stimulation parameter set representations in order to make the fitting process easier and more streamlined.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the



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reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C.

103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

10. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mouchawar et al. (6,738,668) as applied to claim 27 above and further in view of van Lake (5,785,660).

Mouchawar is as explained before. Mouchawar shows an external device for programming operating parameters but fails to specifically disclose a joystick. Attention is directed to van Lake who shows it is well known to use a programming device including a joystick to adjust stimulation parameters of an implantable device (Col. 5, lines 7-23). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Mouchawar to include adjusting the stimulation level using a joystick as taught by van Lake since it is well known in the art to utilize a joystick as an input device for a programmer to adjust stimulation parameters.

#### ***Response to Arguments***

11. Applicant's arguments with respect to claims 1-2, 22-24, 26-33 and 35 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Allowable Subject Matter***

12. Claims 25 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


13. Claims 36-51 are allowed.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Droesch Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Kristen Droesch Mullen  
Patent Examiner  
Temp. Signatory Authority  
Art Unit 3766

kdm